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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,628	06/27/2005	Augustinus Bader	Q-85-446	3519
23373 7590 03/19/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER DAVIS, RUTH A				
ART UNIT 1651		PAPER NUMBER		
MAIL DATE 03/19/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/518,628

**Applicant(s)**

BADER, AUGUSTINUS

**Examiner**

Ruth A. Davis

**Art Unit**

1651

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-32, 34, 36, 37 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-32, 34, 36-37, 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and response filed on December 12, 2007 have been received and entered into the case. Claims 33, 35, 38 – 40 are canceled; claim 53 is added; claims 28 – 32, 34, 36 – 37 and 53 are pending and have been considered on the merits. All arguments have been fully considered.

#### ***Claim Objections***

Claim objections are withdrawn due to amendment.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28, 34, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 36 and 37 are rendered vague and indefinite for depending on a canceled claim.

In claim 36, the terms “a skin” and “a feeder” render the claim indefinite because the terms have not been adequately defined by the claim language or specification.

Claim 28 is rendered vague and indefinite because it is unclear if the claim intends to change the factor by which growth is controlled, as the independent claims requires EPO and

claim 28 requires EPO, or TPO, or GH, or derivatives thereof. Moreover, the claim broadens the scope from which it depends.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 28 – 30, 32, 34 and 36 – 37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Naughton et al. (US 4963489).

Applicant claims a method for in vitro regeneration of tissue, the method comprising multiplying and differentiating adult tissue specific cells in the presence of exogenous EPO or derivative thereof, wherein growth is locally initiated, terminated and structurally guided. The cells are liver cells and growth is induced by treating the cells with EPO, TPO, GH or derivatives thereof. The cells are further cultured with at least one growth factor selected from TGF beta, prostaglandin, GM-CSF, GHRH, TRH, GnRH, CRH, dopamine, ADH, oxytocin, prolactin, adrenocorticotropin, beta-celitropin, lutotropin and/or vasopressin. The method is practiced in the presence of endothelial cells; the cells are grown with a biological matrix or supporting structure; wherein the matrix or support is selected from implants, stents, patch, skin, hydrogel, bone substitute material, allogenic, autologous, xenogenic, synthetic, feeder or fabric tissues; and

the matrix or support has been precolonized with cells selected from tissue specific cells, precursor cells, bone marrow cells, peripheral blood cells, adipose tissue or fibrous tissue.

Naughton teaches methods for generating tissues comprising culturing cells and tissue in vitro wherein the cells proliferate into tissues (abstract) and wherein growth factors such as GH, somatomedins (somatostatin), EPO, and/or prostaglandins (col.12 line 14-27) are added to alter, modulate proliferation and/or differentiation (or the cells are multiplied, differentiated, initiated, terminated and structurally guided by growth factors) (col.12). The added cells may be endothelial cells (abstract), bone marrow cells, liver cells (col.3 line 26-36), fibroblasts, plasma cells (peripheral blood cells), adipocytes (adipose cells), mast cells (tissue specific cell) (col.3 line 45-50), smooth muscle cells, or osteoblasts (col.10). The growth of the cells are guided by a biological matrix which can be used as an implant or transplant material (col.25, abstract). Naughton teaches the cell aggregates are broken up (examples, col.29).

The reference anticipates the claimed subject matter.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 28 – 32, 34, 36 – 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton as evidenced by Chen et al. (US 5076492).

Applicant claims a method for in vitro regeneration of tissue, the method comprising multiplying and differentiating adult tissue specific cells in the presence of exogenous EPO or derivative thereof, wherein growth is locally initiated, terminated and structurally guided. The cells are liver cells and growth is induced by treating the cells with EPO, TPO, GH or derivatives thereof. The cells are further cultured with at least one growth factor selected from TGF beta, prostaglandin, GM-CSF, GHRH, TRH, GnRH, CRH, dopamine, ADH, oxytocin, prolactin, adrenocorticotropin, beta-celotropin, lutotropin and/or vasopressin; or are further cultured with nerve regeneration factors (NGF) or vessel regeneration factors. The method is practiced in the presence of endothelial cells; the cells are grown with a biological matrix or supporting structure; wherein the matrix or support is selected from implants, stents, patch, skin, hydrogel, bone substitute material, allogenic, autologous, xenogenic, synthetic, feeder or fabric tissues; and the matrix or support has been precolonized with cells selected from tissue specific cells, precursor cells, bone marrow cells, peripheral blood cells, adipose tissue or fibrous tissue. The adult tissue specific cells are selected from osteoblasts, fibroblasts, hepatocytes and smooth muscle cells.

Naughton teaches methods for generating tissues comprising culturing cells and tissue in vitro wherein the cells proliferate into tissues (abstract) and wherein growth factors such as GH, somatomedins (somatostatin), EPO, and/or prostaglandins (col.12 line 14-27) are added to alter, modulate proliferation and/or differentiation (or the cells are multiplied, differentiated, initiated, terminated and structurally guided by growth factors) (col.12). The added cells may be endothelial cells (abstract), bone marrow cells, liver cells (col.3 line 26-36), fibroblasts, plasma cells (peripheral blood cells), adipocytes (adipose cells), mast cells (tissue specific cell) (col.3 line 45-50), smooth muscle cells, or osteoblasts (col.10). The growth of the cells are guided by a

biological matrix which can be used as an implant or transplant material (col.25, abstract).

Naughton teaches the cell aggregates are broken up (examples, col.29).

Naughton does not teach the method wherein all of the claimed growth factors are used in the method. However, at the time of the claimed invention, the instant growth factors were well known and used in the art to generate cells into tissues. In support, Chen teaches culturing endothelial cells in the presence of VEGF (abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any of the claimed growth factors in the methods of Naughton as a matter of routine practice as evidenced by

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and Chen to use any of the claimed growth factors in the methods of Naughton with a reasonable expectation for successfully generating tissues in vitro.

### ***Response to Arguments***

Applicant argues that Naughton teaches use of EPO among a list of many without a specific example, and that the reference does not indicate EPO promotes growth of cells. Applicant further argues that it is unexpected that EPO grows adult tissue specific cells and promotes 3D growth of tissues.

However these arguments fail to persuade because Naughton clearly teaches the claimed methods. It is not required that Naughton specifically exemplify all of the teachings, nor to recognize the specific action, particularly since the reference clearly teaches culturing the same cells in the presence of EPO as claimed. Regarding the argued unexpected findings, it is noted

that the claims are not drawn to growing a 3D cell culture, but merely to growing cells in vitro. Thus, the argument is not commensurate in scope with the claims.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651

March 13, 2008